



**UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

SK

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
|-----------------|-------------|----------------------|---------------------|
|-----------------|-------------|----------------------|---------------------|

09/194,930 01/20/99 THOMAS

A 3477-124

000826
ALSTON & BIRD LLP
P O DRAWER 34009
CHARLOTTE NC 28234-4009

QM12/0330

EXAMINER

CADUGAN, J

ART UNIT

PAPER NUMBER

3736

DATE MAILED:

03/30/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/194,930

Applicant(s)
Thomas et al.

Examiner
Joseph A. Cadugan

Group Art Unit
3736



☒ Responsive to communication(s) filed on 20 Jan 1999

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 1-23 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-8, 10-17, and 19-23 is/are rejected.

☒ Claim(s) 9 and 18 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 3736

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 14 April 1999 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56© most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered. The three foreign language patents in German and French were not considered. All references in English were considered.

Specification

2. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 13, 15, 16, 20, 21, and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

Art Unit: 3736

which applicant regards as the invention. Under 35 U.S.C. 101, the claiming of body parts is not permitted. These claims use the language "said target tissue," which positively recites a vague part of the human body. Replacing the word "said" with the word "the" would solve the problem. The use of "said" with body parts should be corrected anywhere in the claims it occurs.

4. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Reference to figures renders the claim vague and indefinite. It is impossible for the Examiner to determine the scope of the claim, as it is unclear what part or parts of the shown waveforms make up the critical subject matter.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-6, 8, 10, 12, 14-17, 19-20 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Grace et al. in G.B. Patent Application GB 2 270 000 A. Grace et al. teach, in claims 10-16, the use of a low frequency, pulsed electromagnetic field to produce a therapeutic effect on a subject. In lines 3-5 of page 5 and lines 8-10 of page 7 of the specification, Grace et al. teach the use of waves that closely resemble those of the body. Figure 5 shows that there is a

Art Unit: 3736

latency period between the pulses, while claim 10 states that the pulsing characteristics can be adjusted, thus adjusting the latency period between the pulses. These latency periods prevent the induction of a time-averaged current in the body, as stated in lines 11-12 of page 7, in order to prevent the unbalancing of the body's systems, and thus preventing neural excitement as the waveforms end. Lines 8-11 of page 4 and claim 15 states that the treatment is repeated with intervals between, which would constitute a refractory period. Lines 5-8 and 18-21 of page 6 and lines 14-22 of page 7 of the specification describe some of the uses of the invention, including pain reduction and fatigue reduction. Claims 12 and 14 describe changing the characteristics of the waveforms over time as part of the therapy. Lines 15-17 of page 4 of the specification and claim 12 teach the increasing of the frequency of the waveform over time.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 11, 13, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grace et al., in UK Patent Application GB 2 270 000 A, as applied to claims 1 and 14, and further in view of Grauvogel, in U.S. Patent 3,768,337. With regard to claims 11 and 21, Grace et al. teach that transient currents are induced in the body in lines 12-13 of page 7. However,

Art Unit: 3736

Grace et al. do not specifically teach using fast rise times to accomplish this, or that the firing of axons causes this. However, it is known in the art that electrical current is passed through the body by way of the firing of axons. Merriam Webster's Medical Desk Dictionary defines an axon as a nerve-cell process that conducts electrical impulses in the body and that firing axons are the process of the transmission of electrical impulses. Grauvogel does teach using waveforms with fast rise times, as shown in Figures 6c, 6d, and 6e. It would have been obvious to one of ordinary skill in the art, at the time of the invention, to use fast rise times in the waveforms of Grace et al. to achieve transient electrical currents in the body.

With regard to claims 13 and 23, Grace et al. teach the use of waveforms that match those naturally in the body, as shown in the above rejection. However, Grace et al. do not specifically teach using DC offsets. However, it is inherent in the Grace et al. publication that a DC offset was used, as it would be difficult to achieve the effects claimed by Grace et al. without a DC offset. A DC offset is necessary to properly emulate the electrical currents in the body, as the axons of the body are never truly "off" unless they are damaged or dead. Grauvogel teaches the use of DC offsets in Figures 6b, 6c, 6d, and 6e, thus showing what Grace et al. omit.

Allowable Subject Matter

9. Claims 9 and 18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 3736

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Loos, in U.S. Patent 5,935,054, teaches the use of low-frequency, time-varying electromagnetic fields to therapeutically treat subjects for several ailments.


Contact Information

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph A. Cadugan, whose telephone number is (703) 305-0879. The examiner can normally be reached Monday through Thursday and alternate Fridays from 7:30 am to 5:00 pm Eastern Time. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cary O'Connor, can be reached at (703) 308-2701. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the TC 3700 receptionist, whose telephone number is (703) 308-0858.

JAC



March 24, 2000


SAMUEL G. GILBERT
PRIMARY EXAMINER